## REMARKS

Claims 19-40 are pending in the present application, with claims 21-37 having been withdrawn from further consideration. By the present Communication, claims 19 and 43 have been amended to define Applicants invention with greater particularity. The amendments and additions add no new matter as the claim language is fully supported by the specification and original claims.

Applicants submit that pending claims 19, 20, and 40-47 are in condition for allowance, and respectfully requests that the claims as amended be entered.

**Rejections under 35 U.S.C. §102**

Applicants respectfully traverse the rejection of claims 19, 20 and 40-45 under 35 U.S.C. §102(e), as allegedly being anticipated by Greene, et al. (U.S. Pat. No. 6,482,408; hereinafter, "Greene"). To anticipate, a single reference must inherently or expressly teach each and every element of claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131.

The Office Action alleges that Greene discloses FGF-15, which has at least 117 consecutive residues that are identical with SEQ ID NO: 4 of the instant invention. According to the Action, the antibodies of Green would inherently bind SEQ ID NO: 4 of FHF-4. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 19 to recite that the antibody specifically binds to a polypeptide consisting of amino acids 1 to 65 of SEQ ID NO: 4. Applicants submit that Greene is absolutely silent with regard to a polypeptide consisting of amino acids 1 to 65 of SEQ ID NO: 4. More specifically, Greene does not disclose an antibody that specifically binds to a polypeptide consisting of amino acids 1 to 65 of SEQ ID NO: 4.

Accordingly, since Greene fails to teach each and every limitation of the claims as amended, Applicants respectfully submit that Greene fails to anticipate the claimed invention, and request withdrawal of the rejection.

Applicants respectfully traverse the rejection of claims 19, 20, 38 and 40-45 under 35 U.S.C. §102(e), as allegedly being anticipated by Hu, et al. (U.S. Pat. No. 5,817,485; hereinafter, "Hu"). To anticipate, a single reference must inherently or expressly teach each and every element of claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131.

The Office Action alleges that Hu discloses antibodies raised against fragments that bind the polypeptide encoded by FGF-10. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicants have amended claim 19 to recite that the antibody specifically binds to a polypeptide consisting of amino acids 1 to 65 of SEQ ID NO: 4. Applicants submit that Hu is absolutely silent with regard to a polypeptide consisting of amino acids 1 to 65 of SEQ ID NO: 4. More specifically, Hu does not disclose an antibody that specifically binds to a polypeptide consisting of amino acids 1 to 65 of SEQ ID NO: 4.

Accordingly, since Hu fails to teach each and every limitation of the claims as amended, Applicants respectfully submit that Hu fails to anticipate the claimed invention, and request withdrawal of the rejection.

**Rejection Under 35 U.S.C. §103**

Applicants respectfully traverse the rejection of claims 19, 20 and 40-47 under 35 U.S.C. §103(a) as allegedly being unpatentable over Greene in view of Harlow et al., (Antibodies a Laboratory Manual, 1989, Cold Spring Harbor Laboratory, Chapter 9, pages 319-358; hereinafter, "Harlow") and Nathans *et al.* (U.S. Pat. No. 5,872,226; hereinafter, "Nathans").

The recent U.S. Supreme Court decision in the *KSR International v. Teleflex, Inc.* (82 USPQ2d 1385), modified the standard for establishing a *prima facie* case of obviousness. Under the *KSR* rule, three basic criteria are considered. First, some suggestion or motivation to modify a reference or to combine the teachings of multiple references still has to be shown. Second, the combination has to suggest a reasonable expectation of success. Third, the prior art reference or combination has to teach or suggest all of the recited claim limitations. Factors such as the

general state of the art and common sense may be considered when determining the feasibility of modifying and/or combining references. Applicants respectfully submit that the criteria for establishing a *prima facie* case of obviousness have not been satisfied.

The Office Action alleges that Green teaches "labeling antibodies with enzymes, radioititopes [*Sic*] and fluorochromes." (Office Action, page 7.) However, as indicated in the Office Action at page 7, Greene does not teach specific detectable labels/ligands. Additionally, as indicated above, Greene is absolutely silent with regard to an antibody that specifically binds to a polypeptide consisting of amino acids 1 to 65 of SEQ ID NO: 4, as is required by the pending claims.

The Office Action relies upon Harlow for allegedly teaching "labeling with radioiodine, biotin, horseradish peroxidase, alkaline phosphatase, beta-galactosidase, fluorsescein and rhodamine." (Office Action, page 8.) The Office Action also relies upon Nathans for allegedly teaching "anti-FHF antibodies can be bound to different carriers include [*Sic*] glass, polystyrene, polypropylene, polyethylene, dextran, nylon, amylases, natural and modified celluloses, polyacrylamides, agarose and magnetite" and that "anti-FHF antibodies can be labeled with enzymes, radioisotopes, fluorescent compounds, colloidal metals, chemiluminescent compounds, phosphorescent compounds and bioluminescent compounds and compounds such as biotin, dinitrophenyl, puridoxal and fluorescein." (Office Action, page 8.) The Office Action concludes that it "would have been *prima facie* obvious to one of ordinary skill in the art to use any available label/ligand and solid phase such as those described by Harlow et al and Nathans et al to label the antibody or immobilize the antibody of Greene et al because Greene et al teach that the antibodies can be labeled and immobilized and such treatment facilitates detection of the antigen or diagnosis of disease." (*Id.*) However, Applicants submit that both Harlow and Nathans are absolutely silent with regard to a polypeptide consisting of amino acids 1 to 65 of SEQ ID NO: 4. More specifically, Harlow and Nathans do not disclose an antibody that specifically binds to a polypeptide consisting of amino acids 1 to 65 of SEQ ID NO: 4, as required by the pending claims.

Accordingly, Applicants respectfully submit that the cited references, either alone or in any combination, do not teach each and every limitation of the claimed invention. As such, even

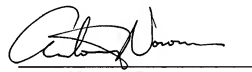
if one of skill in the art were to combine the cited references, the resulting modifications to the method of Green would *not* allow one of skill in the art to produce an antibody that specifically binds to a polypeptide consisting of amino acids 1 to 65 of SEQ ID NO: 4, as required by the pending claims. As such, withdrawal of the rejection is respectfully requested.

**Conclusion**

The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

The Commissioner is hereby authorized to charge the total amount of $940.00 as payment for the Request for Examination fee ($810.00) and One-Month Extension of Time fee ($130.00), large entity, to Deposit Account No. 07-1896. Additionally, the Commissioner is authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-identified Attorney Docket number.

Respectfully submitted,



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